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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,924	12/02/1999	DIDIER SAINT-LEGER	2365-12	6893

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

26

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/449,924

Applicant(s)

SAINT-LEGER, DIDIER

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment C, received by the Office on July 26, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/24329 to Blieszner *et al* (hereinafter WO '329). WO '329 discloses a personal care composition which includes water, dimethicone, a polymeric emulsifier, a water soluble polyol, a pH adjusting agent, an anti-microbial agent, and a chelating agent. WO '329 further discloses that the preferred antimicrobial agent includes 3-iodo-2-propynyl butyl carbamate (p 5, paragraph 2), and that the polyol may be chosen from a group including 1,2,4-butane triol, 1,2,6-hexane triol, and sorbitol (p 11, paragraph 4). Further, in the examples, WO '329 teaches that the polyol and the antimicrobial agent are present in amounts that fall within the range claimed by applicant. In addition, WO '439 teaches that additives, such as fragrances, skin smoothing aids, moisturizers, humectants, emollients, powders (p 14, paragraph 2), silicone oils, and organic base pH adjusting agents can also be included (p 20, example a). Lastly, although the preferred embodiment of the composition disclosed by WO '329 is a wipe, they also teach that the composition may be administered through spraying, dripping, smoothing, massaging, or rubbing.

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It is the position of the examiner that this disclosure is broader than simply a wipe, and allows for other forms of application, and therefore it reads on the limitations of applicant's claim 12.

Applicant's arguments have been fully considered but are not found persuasive.

Applicant has amended the claims to include "further optionally containing an antibacterial agent selected from..." Applicant first argues that the Examiner's apparent reliance on a modification of the cited art to make the presently claimed invention supports the applicant belief that each and every aspect of the presently claimed invention is not taught by the cited art. The examiner respectfully disagrees. The examiner admits to making the statement that it is within the skill of the art that one would use a combination of agents having the same function to obtain either an additive or a synergistic effect. The examiner made this statement referring to the prior art. As stated previously, from the very fact that the cited reference teaches that both 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 3-iodo-2-propynyl butyl carbamate are known as antimicrobial agents, this shows that they each possess a certain degree of antimicrobial activity. The examiner made the assertion to prove that combining two known microbial actives, as done in the cited reference, to obtain a heightened effect, is known in the art. Simply because the reference uses two microbial agents, rather than each agent individually, does not render the use of one agent patentable. As stated previously, a finding that one of the antimicrobial agents is sufficient to produce an antimicrobial effect is not patentable.

Regarding applicant's amendment to the claim, this does not create a patentable distinction. Applicant's amendment uses "optionally" language, which does not require the

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presence of the new limitation. Therefore, the claim as amended does not require anything different than the claims presented previously.

Regarding the rejection of claim 23, this claim has been removed from the anticipation rejection, but it still considered obvious over the cited references. See below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12, 22, and 23 above. WO '329 does not teach the exact polyol claimed in claim 5. However, applicant teaches that many polyols can be used in the formulation and achieve the same effect. Further, WO' 329 does teach the inclusion of some of the polyols claimed by applicant in claim 4. Therefore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any polyol in the formulation disclosed by WO '329, with the expected results being an equally successful antimicrobial composition. Therefore the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The burden is shifted to applicant to disclose the criticality in the specific compound claimed in claim 5 of the instant application.

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Applicant's arguments have been fully considered but are not found persuasive.

Applicant argues that this rejection is moot in view of the unexpected synergistic results shown at pages 6-8 of applicant's instant specification. The examiner respectfully disagrees. The pages pointed to by applicant provide no evidence that one polyol is better than another. Applicant does use the particular polyol of claim 5 in the examples found in the specification. However, this alone is not enough to persuade the Office that this polyol has unexpected results over any other polyol. Absent this specific type of data, the above rejection is maintained.

Claims 1-13 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12, 22, and 23 above, and further in view of US Patent 5,552,425 to Merianos (hereinafter US '425). WO '329 teaches that the composition can be used to clean and disinfect the skin, but does not teach its use as a shampoo. US '425 discloses an antimicrobial composition which comprises 3-iodo-2-propynyl butyl carbamate, as well as a glycol (abstract). US '425 further teaches that their composition can be used as a shampoo (c 36, claim 8). It is the position of the examiner that one of ordinary skill in the art would have been motivated to use the composition disclosed by WO '329 as a shampoo composition, in addition to a skin composition. The composition disclosed by WO '329 must be sensitive to the skin in order to be useful as a skin formulation, and therefore would not be harmful if applied to the scalp. Further, based on the disclosure of US '425, the active ingredient (IPBC) is acceptable in shampoo formulations. One of ordinary skill in the art would have expected a shampoo composition with the same antimicrobial properties achieved by the skin formulation. Therefore

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the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found persuasive.

Applicant argues that each reference teaches the use of DMDMH, while applicant does not require the use of this ingredient. As discussed above, this argument is not found to be persuasive.

Additionally, applicant argues that the limitations of claim 23 are not taught by the reference. The examiner respectfully disagrees. At page 18, paragraph 3 of the WO reference, it is taught that the compositions of their invention are useful for personal cleansing and/ or skin treating applications. It is the position of the examiner that one of ordinary skill in the art would consider inflammatory and/ or desquamating skin disorders to fall within this broad teaching to skin treating applications. Therefore, the cited reference suggests the limitations of this particular claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
October 23, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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